REMARKS

This Amendment is in response to the Office Action, dated August 11, 2009 ("Office Action"). It is respectfully submitted that the application is in condition for allowance. Claims 1, 5, 7 and 8 have been amended; claims 2, 6, 9 and 10 have been canceled; and claims 11-14 have been added by virtue of the present amendment. No new matter has been added. Allowance and reconsideration of the application in view of Applicants' amendment and the ensuing remarks are respectfully requested.

Claims 1 and 5 have been amended to recite the complete name of the polypeptide "PTN" (*e.g.*, "pleiotrophin (PTN)"); and to recite that artificially increasing the expression of PTN is done by transducing the monocytic cell *in vitro* with a retrovirus expressing PTN. No new matter has been added. Support may be found throughout the specification; for example, page 9, second full paragraph, and original claims 2 and 6.

Claims 3 and 7 have been amended to change the claim dependency due to the cancellation of claims 2 and 6. No new matter has been added. Support may be found throughout the specification.

Claims 5, 7 and 8 have been amended to indicate that the endothelial cell is an isolated endothelial cell. No new matter has been added. Support may be found throughout the specification.

Claims 11 and 13 have been added and recite that the transdifferentiation of the monocytic cell into the endothelial cell occurs *in vitro*. No new matter has been added. Support may be found throughout the specification; for example, pages 10-13; and examples on page 17.

Claims 12 and 14 have been added and recite that the transdifferentiation of the monocytic cell into the endothelial cell occurs *in vivo*. No new matter has been added. Support may be found throughout the specification; for example, pages 13-15.

In the Office Action, the Examiner acknowledged Applicants' election of Group II, drawn to a method of transdifferentiating a monocytic cell transduced with a retrovirus expressing PTN, thereby artificially increasing the expression of PTN in the monocytic cell such that the transgenic monocytic cell transdifferentiates into a transgenic endothelial cell. The Examiner also acknowledged Applicants' traversal to the species election and found the arguments persuasive. Thus, the Examiner has withdrawn the species election.

The Examiner reviewed and acknowledged Applicants' priority claims. Applicants thank the Examiner for confirming that the claims of priority are recognized.

The Examiner also confirmed that Applicants' Information Disclosure Statements (filed with the USPTO on October 27, 2006; November 15, 2006; and December 21, 2006, respectively) were considered. Applicants thank the Examiner for returning an initialled copy of the PTO Forms 1449.

The Examiner has required submission of new corrected drawings in compliance with 37 C.F.R. §1.121(d). The Examiner found that Figures 3B, 5C, 5D, 5E and 5F do not photocopy well, yielding essentially opaque panels. The Examiner stated that a skilled artisan, as well as the Examiner, is precluded from evaluating the data on its merit. Accordingly, Applicants are concurrently filing via express mail a Petition to accept color drawings. Included in the Petition are color drawings for Figures 3B, 5C, 5D, 5E and 5F. Applicants respectfully request that the objection be withdrawn in light of the Petition.

Claims 1 and 5 are objected to as containing the abbreviation "PTN" without first identifying the polypeptide by its complete name prior to using the acronym. Claims 1 and 5 have been amended to recite the complete name of the polypeptide "PTN" as "pleiotrophin." Accordingly, Applicants respectfully request withdrawal of this objection.

Claims 5-8 are rejected under 35 U.S.C. §101 as being directed to non-statutory subject matter because they allegedly embrace a human subject. The Examiner requested that the term "isolated" be inserted before the recitation of "endothelial cell." With respect to canceled claim 6, this rejection is rendered moot. Applicants traverse this rejection with respect to claims 5 and 7-8. While Applicants do not concede to the merits of the Examiner's rejection, in an effort to advance prosecution, claims 5 and 7-8 have been amended to describe the endothelial cell as an "isolated" endothelial cell. Accordingly, Applicants respectfully request withdrawal of this rejection.

Claims 1 and 5 are rejected under 35 U.S.C. §112, second paragraph, as allegedly being incomplete for omitting essential steps. In particular, the Examiner found that the means by which the expression of PTN is artificially increased in the monocytic cell such that the monocytic cell transdifferentiates into an endothelial cells is omitted. Applicants respectfully traverse this rejection.

While Applicants do not concede to the merits of the Examiner's rejection, in an effort to advance prosecution, laims 1 and 5 have been amended to recite that PTN expression is increased "by transducing the monocytic cell with a retrovirus expressing PTN." Accordingly, Applicants respectfully request withdrawal of this rejection under §112, second paragraph.

Claims 1-8 are rejected under 35 U.S.C. §112, first paragraph, as allegedly lacking enablement. The Examiner conceded that the specification is enabled for a method of transdifferentiating a monocytic cell into an endothelial cell by transducing the monocytic cell *in vitro* with a retrovirus expressing PTN such that the monocytic cell transdifferentiates into an endothelial cell. The Examiner also conceded that the specification is enabled for the endothelial cell produced by the same method. However, the Examiner contended that the specification does not reasonably enable the full scope of the claims for reasons of record. In making the enablement rejection, the Examiner cited the following references for their alleged teachings on the state of the art:

Orkin *et al.* (NATIONAL INSTITUTES OF HEALTH REPORT, December 7, 1995);

Patterson (STATEMENT OF AMY PATTERSON, M.D., February 2000);
Deonarain (EXPERT OPINION ON THERAPEUTIC PATENTS, (1998), 8:53-69);
Verma and Somia (NATURE, (1997), 389:239-242);
Verma and Weitzman (ANNUAL REVIEW IN BIOCHEMISTRY, (2005), 74:711-738);
Goncalves (BIOESSAYS, (2005), 27:506-517);
Johnson-Saliba *et al.* (CURRENT DRUG TARGETS, (2001), 2:371-399);
Shoji *et al.* (CURRENT PHARMACEUTICAL DESIGN, (2004), 10(7):785-796); and
Bestor (JOURNAL OF CLINICAL INVESTIGATION, (2000), 105:409-411).

Applicants respectfully traverse this rejection.

Applicants submit that a limitation of the claims is that the monocytic cell transdifferentiates into an endothelial cell. While Applicants do not concede to the merits of the Examiner's rejection or the relevance of the references cited for the alleged teachings on the state of the art relating to gene therapy, Applicants submit that the claims, as amended, are fully enabled by the specification as filed. Claim 1, as amended, recites that the method of artificially increasing the expression of PTN is by "transducing the monocytic cell *in vitro* with a retrovirus expressing PTN." As acknowledged by the Examiner, an *in vitro* method of transducing the monocytic cell with a retrovirus expressing PTN is fully enabled by the specification. Thus, claims 3 and 4 that depend from claim 1 are also enabled. Claim 5 is similarly amended and is thus, fully enabled by the specification. Claims 7 and 8, which depend from claim 5 are also enabled.

While new claims 11-14 are not subject to the rejection, in an effort to advance prosecution, Applicants submit the following remarks. Claims 11 and 13, directed to *in vitro* transdifferentiation, are fully enabled by the specification (*e.g.*, pages 10-13; and examples on page 17) and as evidenced by the Examiner's acknowledgement. Claims 12 and 14, directed to *in vivo* transdifferentiation, are also fully enabled by the specification. For instance starting on page 13, the specification discusses the transplantation of RAW cells expressing PTN onto CAM of E7 (quail) embryos. The implantation led to the cells' integration into newly developed quail vascular tree and "PTN-expressing cells became incorporated into large and small blood vessels at various branches." Further, RAW cells expressing PTN injected into stage 16-17 chick

embryos show their capacity to integrate into developing blood vessels. In sum, the specification shows that the *in vivo* function studies evidences PTN-expressing monocytes have the ability to hone to and become integrated into newly developing blood vessels and the transdifferentiation of monocytes into endothelial cells is not mediated by cell fusion (*see e.g.*, page 15). In light of the foregoing, Applicants respectfully request withdrawal of this rejection under §112, first paragraph.

Claims 5-8 are rejected under 35 U.S.C. §102(b) as being anticipated by Pavlov *et al.* (Molecular and Cellular Neuroscience, (2002), 20(2):330-342) as evidenced by Hellstrom *et al.* (Development, (1999), 126(14):3047-3055, Abstract only). The Examiner alleged that these claims reasonably embrace endothelial cells within an organism. The Examiner argued that Pavlov *et al.* teaches a transgenic mouse expressing the pleiotrophin (PTN) expression operably linked to the PDGF-beta chain promoter. Although the Examiner concedes that Pavlov *et al.* fails to teach PTN expressed in endothelial cells, the Examiner contends that Hellstrom *et al.* teaches that PDGF-beta is naturally expressed in endothelial cells. Thus, the Examiner reasoned that endothelial cells of the PTN transgenic mouse inherently express PTN. The Examiner also conceded that Pavlov *et al.* does not teach the endothelial cells that are produced by the process of transdifferentiating RAW or THP-1 monocytic cells via a retrovirus expressing PTN. However, the Examiner argued that the method in which the endothelial cells were produced is immaterial to their patentability because these are product-by-process claims. With respect to canceled claim 6, this rejection is rendered moot. With respect to claims 5 and 7-8, Applicants respectfully traverse this rejection.

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. MPEP §2131 (citing Verdegaal Bros. v. Union Oil Co. of California, 814 F.2d 628, 631 (Fed. Cir. 1987). In a product-by-process claim, "the structure implied by the process steps should be considered when assessing the patentability of the product-by-process claims over the prior art, especially...where the manufacturing process steps would be expected to impart distinctive structural characteristics to the final product." MPEP §2113 (citing *In re* Garnero, 412 F2d 276, 279, 162 USPQ 221, 223 (CCPA 1979).

Applicants submit that claims 5 and 7-8, as amended, are not anticipated by Pavlov *et al.* as evidenced by Hellstrom *et al.* Claims 5 and 7-8 have been amended to indicate that the endothelial cell is an "isolated" endothelial cell. Pavlov *et al.* as evidenced by Hellstrom *et al.* do not teach isolated endothelial cells expressing PTN.

Additionally, Applicants submit that while the patentability of product-by-process claims is based on the product itself, the Examiner's assertion that the method in which the endothelial cells were produced is immaterial to their patentability is not accurate. In claim 5, the method involves transducing a retrovirus expressing PTN. Accordingly, the endothelial cell would comprise the transduced retrovirus expressing PTN. The endothelial cell produced by the method is indeed different in structure than the endothelial cell cited by the Examiner because the endothelial cell described by Pavlov *et al.* does not have a transduced retrovirus expressing PTN. In light of the foregoing, Applicants respectfully request withdrawal of this rejection under §102(b).

Claims 5-8 are rejected under 35 U.S.C. §102(b) as being anticipated by Abbot *et al.* (ARTHRITIS AND RHEUMATISM, (April 1992), 35(4):401-406) as evidenced by Pufe *et al.* (ARTHRITIS AND RHEUMATISM, (2003), 48(3):660-667). The Examiner found that Abbot *et al.* teaches isolated synovial endothelial cells. Although the Examiner conceded that Abbot *et al.* fails to teach endothelial cells that express PTN, the Examiner contends that Pufe *et al.* taught that synovial endothelial cells endogenously express PTN. The Examiner also conceded that Abbot *et al.* does not teach the endothelial cells that are produced by the process of transdifferentiating RAW or THP-1 monocytic cells via a retrovirus expressing PTN. However, the Examiner notes that the method in which the endothelial cells were produced is immaterial to their patentability. With respect to canceled claim 6, this rejection is rendered moot. With respect to claims 5 and 7-8, Applicants respectfully traverse this rejection.

As discussed above, the Examiner's assertion that the method in which the endothelial cells were produced is immaterial to their patentability is not accurate. In claim 5, the method involves transducing a retrovirus expressing PTN. Accordingly, the endothelial cell would comprise the transduced retrovirus expressing PTN. The endothelial cell produced by the method is indeed different in structure than the

endothelial cell cited by the Examiner because the endothelial cell described by Abbot *et al.* does not have a transduced retrovirus expressing PTN. In light of the foregoing, Applicants respectfully request reconsideration and withdrawal of this rejection under §102(b).

Claims 1-2 are rejected under 35 U.S.C. §103(a) as being unpatentable over Havemann *et al.* (U.S. Patent Publication No. 2002/0098166) in view of Souttou *et al.* (JOURNAL OF CELLULAR PHYSIOLOGY, (2001), 187:59-64) and Powers *et al.* (JOURNAL OF BIOLOGICAL CHEMISTRY, (2002), 277(16):14153-14158). The Examiner alleged that Havemann *et al.* discloses a method of obtaining endothelial cells by culturing mononuclear cells (*e.g.*, monocytes) from the blood with a growth factor for endothelial cells, wherein the growth factor is pleiotrophin; and the use of a viral vector to transform a gene encoding a growth factor to promote the endothelialization of injured vessels or angiogenesis. The Examiner conceded that Havemann *et al.* does not disclose *ipsis verbis* a retroviral vector, but argued that one of ordinary skill in the art recognizes retroviral vectors are used to express an active compound and Havemann *et al.* discloses the use of retroviral elements for the expression vector. Further, the Examiner cited Souttou *et al.* for its disclosure that PTN is an angiogenic factor and Powers *et al.* for its disclosure that PTN has autocrine and paracrine stimulatory activities. Accordingly, the Examiner concluded, for reasons of record, that "the invention as a whole is *prima facie* obvious." Applicants respectfully traverse this rejection.

In determining whether a claimed invention is prima facie obvious, the Examiner must not use impermissible hindsight; rather "the content of the prior art must be determined at the time the invention is made." MPEP §2141.01(III). Additionally, "in determining the differences between the prior art and the claims, the question…is not whether the differences themselves would have been obvious, but whether the claimed invention as a whole would have been obvious. MPEP §2141.02(I), emphasis in original, (citing Stratoflex, Inc., v. Aeroquip Corp., 713 F.2d 1530 (Fed. Cir. 1983). Further, "distilling an invention down to the 'gist' or 'thrust' of an invention disregards the requirement of analyzing the subject matter 'as a whole.'" Moreover, "treating the

advantage as the invention disregards statutory requirement that the invention be viewed 'as a whole.'" MPEP §2141.02(II), citing W.L. Gore & Associates, Inc. v. Garlock, Inc., 721 F.2d 1540 (Fed. Cir. 1983) and Jones v. Hardy, 727 F.2d 1524, 1530 (Fed Cir. 1984). Additionally, "the mere fact that references can be combined or modified does not render the resultant combination obvious unless the results would have been predictable to one of ordinary skill in the art." MPEP §2143.01 (citing KSR International Co. v. Telefex Inc., 550 U.S. 398, 82 USPQ2d 1385 (2007)). As such, a "reasonable expectation of success is required." MPEP §2143.02. Furthermore, a patent cannot be relied upon to the extent that the scope of its disclosure does not reasonably suggest those aspects relied upon in the rejection. MPEP §2123 (citing Merck & Co. v. Biocraft Laboratories, 874 F.2d 804, 10USPQ2d 1843 (Fed. Cir.), *cert. denied*, 493 U.S. 975 (1989)).

Applicants submit that Havemann *et al.* does not reasonably teach the use of PTN to obtain endothelial cells. Havemann *et al.* discloses a method of culturing mononuclear cells by "culturing the cells in a culture medium comprising one or more of gangliosides, phospholipids, glycolipids and growth factors for endothelial cells, including those growth factors which influence differentiation, survival, migration and vascularization." (*See* Havemann *et al.*, paragraph 0015; emphasis added.) The disclosure with respect to PTN was in the context of a possible growth factor, selected from a list of at least 33 other growth factors, that can be used in the culture medium for the mononuclear cells; growth factors that influence differentiation, survival, migration and vascularization. (*See* Havemann *et al.*, *e.g.*, paragraphs 0037, 0073 and 0074.) There is no indication on which of the "one or more of gangliosides, phospholipids, glycolipids and growth factors for endothelial cells" is responsible for differentiation of the mononuclear cells into endothelial-like cells, as opposed to survival, migration and/or vascularization. As such, Havemann *et al.* does not reasonably teach the use of PTN as a growth factor responsible for differentiating monocytic cells into endothelial cells.

Applicants further submit that Havemann *et al.* does not reasonably disclose a retroviral vector to transform a gene encoding a growth factor to promote the endothelialization of injured vessels or angiogenesis into the monocytic cells.

Havemann *et al.* discusses cells for use in gene therapy wherein there exist as a possibility that the mononuclear cells are transfected with a nucleic acid construct for gene therapy. (Havemann *et al.* paragraph 0032.) However, as shown in Example 5 of Havemann *et al.*, the transfection of the effector gene is into the endothelial cells, not the mononuclear cells. This is further evidence by the sections on preparation and immortalization of endothelial cells and preparation of genetically modified endothelial cells for prophylaxis and/or therapy (Havemann *et al.*, paragraphs 0060-0242.) It is in the context of using endothelial cells that "genes for angiogenesis factors" were noted as potential effector genes (Havemann *et al.*, paragraphs 0186-0191). As such, Havemann *et al.* does not reasonably disclose transducing a monocytic cell with a gene for angiogenesis factor. Therefore, one of ordinary skill in the art would not look to combine the teachings of Havemann *et al.* with Souttou *et al.* and Powers *et al.* to select PTN as the angiogenesis factor. Accordingly, claims 1-2 are not rendered *prima facie* obvious.

While Havemann *et al.* allows for the possibility that the mononuclear cells are transfected with the nucleic acid construct for gene therapy, the rationale provided by the Examiner does not support the rejection under §103(a). Applicants remind the Examiner that the mere fact that references can be combined does not render the combination obvious because the results would not have been predictable to one of ordinary skill in the art and there would not be a "reasonable expectation of success" by one of ordinary skill in the art.

Indeed, the Examiner has not shown that one of ordinary skill in the art would find that using a monocytic cell (as opposed to an endothelial cell) transduced with a retrovirus expressing PTN would predictably transdifferentiate the monocytic cell into an endothelial cell. Havemann *et al.* made no indication on which of the "one or more of gangliosides, phospholipids, glycolipids and growth factors for endothelial cells" is responsible for differentiation of the mononuclear cells into endothelial-like cells. In its examples, only VEGF and bFGF were added in the culture media. (Havemann *et al.*, paragraphs 0247-0249.) Thus, it would not be reasonably predictable to one of ordinary skill in the art that PTN alone can transdifferentiate a monocytic cell into an endothelial cell.

Further, the Examiner has not shown that one of ordinary skill in the art would believe that there is a reasonable expectation of success in using a monocytic cell (as opposed to an endothelial cell) transduced with a retrovirus expressing PTN, to effect the gene therapy contemplated by Havemann *et al.*; specifically, to effect the "Therapy of Disorders of the Blood Clotting and Blood Circulation System." (Havemann *et al.*, paragraphs 0186 and 0191.) In light of the teachings in Havemann *et al.* explained *supra*, one of ordinary skill in the art would not find any reasonable expectation of success for the combination of Havemann *et al.*, Souttou *et al.* and Powers *et al.* to use only PTN to transdifferentiate a monocytic cell into an endothelial cell.

As indicated above, the Examiner must not use impermissible hindsight in order to reject the claims. In this instance, it appears that it would require impermissible hindsight in order to arrive at the claimed invention because the content of the prior art determined at the time the invention is made would not lead to the invention as claimed because, *inter alia*, there would be no reasonable expectation of success. Additionally, it appears that the rejection is prefaced on an alleged obvious difference in the teaching of the prior art and the claimed invention; for example, the selection of PTN as the angiogenesis factor. However, the invention as a whole – transdifferentiation of monocytic cells into endothelial cells by transducing a retrovirus expressing PTN – would not be obvious in view of the combination of Havemann *et al.*, Souttou *et al.* and Powers *et al.* In light of the foregoing, Applicants respectfully request reconsideration and withdrawal of this rejection under §103(a).

Claim 3 is rejected under 35 U.S.C. §103(a) as being unpatentable over Havemann *et al.* (U.S. PATENT PUBLICATION NO. 2002/0098166) in view of Souttou *et al.* and Powers *et al.*, as applied to claims 1-2 *supra*, and in further view of Kume *et al.* (GENE THERAPY, (2000), 7:1193-1199). The Examiner conceded that neither Havemann *et al.*, Souttou *et al.* nor Powers *et al.* teach the retrovirus expression vector to be a bicistronic retrovirus and the Examiner contended that Kume *et al.* taught the use of bicistronic retroviral vectors containing a marker gene (*e.g.*, green fluorescent protein). Thus, the Examiner concluded that it would have been obvious to one of ordinary skill in the art to substitute the retroviral expression vector by Havemann *et al.* with a bicistronic

retroviral expression as taught by Kume *et al.* Applicants respectfully traverse this rejection.

Applicants submit that the combination of Havemann *et al.*, Souttou *et al.*, Powers *et al.* and Kume *et al.* would not render claim 3 obvious. As discussed above, the combination of Havemann *et al.* Souttou *et al.* and Powers *et al.* would not render claim 1 obvious because there would not be, among other things, any predictability or any expectation of success for the transduced monocytic cell to transdifferentiate into an endothelial cell. Since claim 3 depends from claim 1, it would similarly not be obvious as the determination of obvious of the claim also require, among other things, the predictability that a monocytic cell transduced with a retrovirus expressing PTN would transdifferentiate into an endothelial cell and the same expectation of success. Since there is no predictability and no expectation of success from the combination of Havemann *et al.*, Souttou *et al.* and Powers *et al.*, there will not be any predictability or expectation of success for the combination of Havemann *et al.* Souttou *et al.*, Powers *et al.* and Kume *et al.*; although Applicants do not concede that it is proper to combine Kume et al. with Havemann *et al.*, Souttou *et al.*, and Powers *et al.* In light of the foregoing, Applicants respectfully request reconsideration and withdrawal of this rejection under §103(a).

Claim 4 is rejected under 35 U.S.C. §103(a) as being unpatentable over Havemann *et al.* in view of Souttou *et al.*, Powers *et al.* and Kume *et al.*, as applied to claims 1-3 *supra*, and in further view of Pufe *et al.*, Howett *et al.* (U.S. PATENT NO. 6,309,848) and Eslami *et al.* (JOURNAL OF VASCULAR SURGERY, (2001), 34:923-929). The Examiner conceded that neither Havemann *et al.*, Souttou *et al.*, Powers *et al.*, nor Kume *et al.* teach the monocytes to be THP-1 monocytes. However, the Examiner contended that THP-1 cells are taught by Pufe *et al.* as being responsive to PTN stimulation; by Howett *et al.* as being useful for implantation; and by Eslami *et al.* as being capable of binding to injured human vein grafts. The Examiner concluded that it would have been obvious to one of ordinary skill in the art to substitute a first mononuclear/monocytic cell as taught by Havemann *et al.* with a second monocytic cell

(specifically, THP-1) as taught by Pufe *et al.* Applicants respectfully traverse this rejection.

Applicants suspect and submit that Kume *et al.* was erroneously applied to the rejection of claim 4. The Examiner has applied Kume *et al.* to reject claim 3; however, claim 4 does not depend from claim 3. As such, Kume *et al.* would be in applicable to claim 4. Nonetheless, Applicants submit that the combination of Havemann *et al.*, Souttou *et al.*, Powers *et al.*, Kume *et al.*, Pufe *et al.*, Howett *et al.* and Eslami *et al.* would not render claim 4 obvious. As discussed above, the combination of Havemann *et al.* Souttou *et al.* and Powers *et al.* would not render claim 1 obvious, because, among other things, there would not be any expectation of success. Since claim 4 depends from claim 1, it would similarly not be obvious as the determination of obvious of the claim also require, among other things, the predictability that a monocytic cell transduced with a retrovirus expressing PTN would transdifferentiate into an endothelial cell and the same expectation of success. Since there is no predictability and no expectation of success from the combination of Havemann *et al.*, Souttou *et al.*, and Powers *et al.*, there will not be any predictability or expectation of success for the combination of Havemann *et al.* Souttou *et al.* Powers *et al.*, Kume *et al.*, Pufe *et al.*, Howett *et al.* and Eslami *et al.*; although Applicants do not concede that it is proper to combine Kume *et al.*, Pufe *et al.*, Howett *et al.* and Eslami *et al.* with Havemann *et al.*, Souttou *et al.*, and Powers *et al.* In light of the foregoing, Applicants respectfully request reconsideration and withdrawal of this rejection under §103(a).

//...p. 16.

All of the claims remaining in the application are now believed to be allowable. Favorable consideration and a Notice of Allowance are earnestly solicited. If for any reason Examiner finds the application other than in condition for allowance, Examiner is requested to call the undersigned attorney at the Los Angeles telephone number (213) 633-6800 to discuss the steps necessary for placing the application in condition for allowance.

Respectfully submitted,
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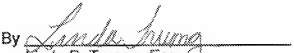
By 
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